
Confidentiality of Substance Use Disorder Patient Records Rule

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Topics:

- **General Overview**
- **Consent**
- **Special Types of Consent**
- **Disclosures without Consent**

Part 2 Rule General Overview

Part 2 Terminology

Patient Identifying Information

- Relates to Patient of a Part 2 Program
- Individually identifiable (per HIPAA)
- Patient received diagnosis, treatment, referral for SUD

Part 2 Program

- Holds itself out as providing SUD treatment
- Receives Federal assistance
- May be a unit of larger facility (“Mixed-Use” facility)

Third-Party Payer

- Entity that pays for Part 2 patient on the basis of contractual relationship
- Health insurers, self-funded health plans, etc.

Lawful Holder

- Any entity in lawful possession of Patient Identifying Information

General Rule—Consent Required

Part 2 Program needs consent to disclose PII

- Consent must specify purpose for permitted disclosure

Recipient may USE PII for specified purpose

Recipient needs consent to re-disclose PII

- Consent must specify purpose for re-disclosure

Exceptions to Consent Requirement

Audit & Evaluation

- Audit or evaluation of Lawful Holder
- Recipient agreement required

Research

- In accordance with HIPAA research provisions

Medical Emergencies

- Bona fide medical emergency

Part 2 Rule Consent

Consent: Nine Elements

1. Patient name
2. Who can use or disclose PII
3. Type and kind of information to be disclosed
4. Right to revoke
5. Date or condition for expiration of consent
6. Signature
7. Date
8. Purpose of the disclosure—recipient's permitted uses
9. The recipient

Consent: 4 types of Permitted Recipients

1. Named “Intermediary”

2. Named Third-Party Payer

- Acme Health Plan (**not** “my health plan”)

3. Named entity with Treating Provider Relationship

- Betty Ford Clinic;
- Anytown General Hospital

4. A named individual

- Ms. Jane Doe
- Dr. Jerome Adams

Condition to Disclosure by Consent: Notice

- Notice that Part 2 applies (“Part 2 Disclaimer”)
 - Must accompany each disclosure of PII permitted by consent
- General warning ***not*** sufficient
- Two options, but ***must be verbatim***
 - Short form (sentence: 10 words, 55 characters):
42 CFR part 2 prohibits unauthorized disclosure of these records
 - Long form (paragraph: 143 words, 900+ characters—see next slide)

Part 2 Disclaimer (long form)

This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65.

Two Special Types of Consent

Payment & Health Care Operations Consent

Permitted purpose in consent

- Purpose is recipient's "payment & health care operations activities"

Permits re-disclosure (subject to contract terms)

- To contactors & subcontractors (*e.g.*, business associates)
- Names or other designations of contractors are **not** required

Part 2 Disclaimer required

Permits disclosure directly to contractor/subcontractor

Payment & Health Care Operations Consent

(Limited) Alignment with HIPAA

- Allows contractors to **use**, but not **re-disclose** PII
- Allows some (not all) Payment & Health Care Operations Activities

Activities **not** permitted by consent:

- Case management & care coordination
- Utilization review and others not listed, but not explicitly prohibited

Contractor/subcontractor terms

- Comply with Part 2 Rule
- Implement appropriate safeguards
- Report unauthorized use, disclosure or breach of PII
- No re-disclosure (except to Third-Party Payer or subcontractor)

Payment & Health Care Operations Consent

Use with Business Associates for your own activities

- Add Part 2 terms to business associate agreements
- Provide Part 2 Disclaimer

Use for disclosures to ASO Accounts/their vendors

- Part 2 terms in ASO account's business associate agreements
- Part 2 Disclaimer

Use for Stop-Loss Carriers

- Disclosures for payment/health care operations
- Carrier not a business associate, but *is* a contractor
- Subject to Part 2 terms; provide with Part 2 Disclaimer

Intermediary Consent

Disclose to “intermediary”—re-disclose to “participant”

- Intermediary is **not** a health care provider or Third-Party Payer
- Intermediary is entity “such as” Health Information Exchange or research institution

Intermediary consent

- Must specify name of intermediary
- Must specify permitted re-disclosures
- Must provide notice of right to accounting of re-disclosures (when applicable)

Intermediary Consent

Permitted recipients of re-disclosures:

- Named ***individual*** “participant”
- Named entity “participant” w/ Treating Provider Relationship
- General designation of “participants” w/ Treating Provider Relationship

Disclosure accounting for general designation

- Consent must describe disclosure accounting right
- List of disclosures: recipient, date, and brief description of PII
- Intermediary must respond within 30 days

Intermediary Consent

Use for case management/care coordination

- Name case manager as intermediary
- Permit re-disclosure to treating providers—general designation
- Purpose of consent: case management/care coordination
- Intermediary must manage re-disclosure accounting right

Getting case management/care coordination consent

- Separate consent
- Part of single, comprehensive consent

Disclosure of PII Without Consent

Disclosure Without Consent

Audit or evaluation of Lawful Holder by:

- Gov't agency that provides financial assistance to Lawful Holder
- Gov't agency that regulates Lawful Holder
- Third-Party Payers covering patients at Part 2 Program
- Other entities that provide financial assistance to Lawful Holder

“Evaluation”

- Not defined

Disclosure Without Consent

Audit or evaluation

- May be conducted by contractor or subcontractor

Subject to written agreement to:

- Maintain and destroy PII per Part 2 requirements
- Retain records in accordance with applicable law
- Re-disclose PII only to Lawful Holder
- Use only for audit/evaluation or Part 2 Court Order

Audit and Evaluation

Health Plan's utilization review

- Plan request for PII to conduct **evaluation** of Utilization
- Plan must agree to required terms

DOI/CMS/AG inquiry

- Request for PII for complaints, Market Conduct Exams, etc.
- Gov't agency must agree to required terms

ASO Account's audit of TPA

- Third-party vendor may conduct audit
- Account/vendor must agree to required terms
- Alternative to Payment/Health Care Operations consent

All Payers Claims Databases

Disclosure permitted for “scientific research”

- To covered entity (or BA) in compliance with HIPAA research provisions; or
- To an entity that:
 - Conducts research regulated by federal gov’t and
 - Complies with HHS regulations on protection of human subjects

APCD as covered entity? Business associate?

APCD research regulated by Federal agency?

Consent is only other alternative

Questions?

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